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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,468	09/12/2000	Allan S. Lau	4099-0002.31	6858

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/26/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/660,468

Applicant(s)

LAU ET AL.

Examiner

David S Romeo

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-- The MAILING DATE f this c mmunication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,10 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,9,10 and 25-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

The amendment filed January 30, 2002 (Paper No. 7) has been entered. In Paper No. 7 it was stated that "applicants also cancelled claims 3-8". In the paper filed June 5, 2002 (Paper No. 9) it was reiterated "that Applicants had requested the cancellation of claims 3-8 in the Reply filed on 01/30/02). Accordingly, claims 3-8 have been cancelled. Claims 1, 2, 9, 10, 25-29 are pending.

Applicant's election of group CXCIX, claim 1-10, to the extent that they are drawn to a composition comprising IFN- α and IFN- β , in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9, 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See page 17, line 6. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may

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become aware in the specification. The application cannot issue until it is in compliance.

Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as “residues 14 to 243 of SEQ ID NO:23” is permissible and the fragment need not be separately presented in the “Sequence Listing.”

Correction is required.

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Information Disclosure Statement

The information disclosure statement filed March 1, 2001 (Paper No. 3) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the “OTHER ART” referred to therein has not been considered because copies of the publications were not provided.

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Claim Objections

Claim 25 is objected to because of the following informalities: the term “cytokines” is misspelled. Appropriate correction is required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- 5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau (n10) in view of Der (u10). Lau discloses a method for enhancing the production of interferon in cell culture. The method comprises culturing a mammalian cell capable of producing the interferon (paragraph bridging pages 6-7), wherein the cells are any number of known cell cultures, U937 and Namalwa cells being particularly suitable (page 8, full paragraph 1). The cells are modified by transfection with a vector containing a PKR gene under the control of a constitutive or inducible promoter, wherein the PKR is overexpressed and above normal levels of PKR are obtained (paragraph bridging pages 7-8). The PKR-overexpressing cells are treated with an inducer to induce expression of the interferons and the interferon is then isolated (paragraph bridging pages 8-9). The cells may be primed prior to induction by the addition of a priming agent (paragraph bridging pages 8-9). Over-expression of the PKR protein induces overproduction of the IFN- α and IFN- β interferons (sentence bridging pages 3-4). These steps are generally followed by purifying or isolating the interferon produced (page 7, lines 6-7; page 8, line 28). Culture supernatants are collected and assayed for interferon (page 5, last sentence). Purifying the interferon would inherently encompass collection of the culture supernatants because the culture supernatants are where the interferon is found. In summary, Lau discloses a composition comprising IFN- α and IFN- β .

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U937 cells make IFN- α and IFN- β , as evidenced by Der at sentence bridging pages 8843-8844. U937 cells are human cytokine producing cells, as evidenced by the present specification at page 7, full paragraph 1.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10, 25, 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Kurimoto (a10) in view of Shimizu (b10). Kurimoto discloses that the combination of HuIFN- γ with HuIFN- α and/or HuIFN- β augments the antiviral, cytostatic and antioncotic activities of HuIFN- γ (column 2, full paragraph 4) and discloses the preparation of HuIFN- γ by affinity chromatography (column 13, Example B-2(3)). Kurimoto is silent with respect the affinity purification of HuIFN- α and/or HuIFN- β . Shimizu discloses the affinity purification of HuIFN- α and HuIFN- β (column 83, Preparative Example 16). Shimizu is silent with respect to the combination of HuIFN- γ with HuIFN- α and/or HuIFN- β . However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a composition comprising HuIFN- γ with HuIFN- α and/or HuIFN- β , using affinity purified HuIFN- γ , as taught by Kurimoto, and using affinity purified HuIFN- α and HuIFN- β , as taught by Shimizu, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this combination because the combination of HuIFN- γ with HuIFN- α and/or HuIFN- β augments

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the antiviral, cytostatic and antioncotic activities of HuIFN- γ . Claims 1, 2, 10, 25 are drafted in the product-by-process format. The references do not describe the production of the composition using methods identical to that recited in claims 1, 2, 10, 25. However, the recitation of a process limitation in claims 1, 2, 10, 25 is not viewed as positively limiting the claimed product composition absent a showing that the process of making recited in claims 1, 2, 10, 25 imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is upon the applicants to establish a patentable distinction between the claimed and referenced products. The invention is prima facie obvious over the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "overproduction" or "overproducing" in claim 1 is a relative term which renders the claim indefinite. The term "overproduction" or "overproducing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

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Claim 10 is indefinite since it depends from a canceled claim, and thus makes no sense, since it is incomplete. The metes and bounds are not clearly set forth.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 10, 25, 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 15-22 of copending Application No. 10105100. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are generic to and fully encompass the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

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IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
AUGUST 24, 2002